

Exhibit 5

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.,
PELVIC REPAIR SYSTEMS PRODUCTS
LIABILITY LITIGATION

MDL NO. 2366

This Document Relates to All
Cases

DEPOSITION OF STEPHEN H. SPIEGELBERG, PH.D.

Wednesday, January 14th, 2015

9:30 a.m.

Held At:

Murphy & Riley, PC
101 Summer Street
Boston, Massachusetts

REPORTED BY:

Maureen O'Connor Pollard, RMR, CLR, CSR

1 Q. Can you tell me?

2 A. The black specks that I observed in
3 the meshes were not black specks per se, as in
4 terms of inclusions, rather were just
5 reflections that are often inherent in circular
6 surfaces.

7 Q. And did you perform independent
8 testing to verify that?

9 A. Yes, I did.

10 Q. And could you describe that to me?

11 A. You take the mesh and place it in an
12 optical microscope, and then rotate the mesh
13 under the optical microscope and see if the
14 black specks move or disappear, which they did.

15 Q. Did you produce any photographs or
16 methods relating to the method and the
17 conclusions that you just described?

18 A. No.

19 Q. So I read the report and I didn't
20 see -- I didn't see any reference to you doing
21 that testing. Is that in there?

22 A. No, it's not in there.

23 Q. Was the examination that you did, was
24 that performed after your report was submitted?

25 A. No, it was not.

1 Q. So you did the examination. So at
2 some point you learned that Plaintiffs' experts
3 had mentioned that they saw black specks under
4 microscopic examination, is that right?

5 A. That's correct.

6 Q. And then after you heard about the
7 black specks, you took it upon yourself to try
8 to perform the same thing that Plaintiffs'
9 experts did?

10 A. I don't know if it's the same thing
11 that they did, but I did a microscopic
12 examination of the meshes.

13 Q. Did you review the photographs -- and
14 this is Dr. Dunn, is that right?

15 A. I believe so.

16 Q. Did you unravel the mesh at all and
17 then look at it under the microscope?

18 A. Yes, I did.

19 Q. And for this examination that you did
20 on black specks?

21 A. Yes.

22 Q. So you took the -- you undid the knit,
23 and you actually saw little strands of
24 polypropylene that had come undone?

25 A. Yes, I did.

1 Q. And you examined them under a
2 microscope, and you saw no black specks?

3 A. I saw the black specks come and go
4 depending on the orientation I held them in the
5 microscope.

6 Q. And did you take it upon yourself to
7 cut open the monofilament and actually confirm
8 that there were no black specks in there?

9 A. Can you explain a little bit more what
10 you mean?

11 Q. Sure.

12 So under a microscope, if you've
13 unravelled the mesh and you see the monofilament
14 there, so this is a monofilament mesh and I
15 assume you were looking at -- I'm sorry, can you
16 tell me what kind of mesh you were looking at?

17 A. It was monofilament.

18 Q. It was a monofilament.

19 Was it the Advantage, or the Polyform?

20 A. This would have been the Polyform.

21 Q. And this was Polyform that had been
22 supplied to you by the Defendant?

23 A. Yes.

24 Q. And so you grabbed a sample the size
25 of a stamp?

1 A. Approximately. A little bit smaller.

2 Q. Smaller than a stamp.

3 And you did your examination of the
4 size of the stamp first and then you unravelled,
5 or how did it go?

6 A. Exactly that way.

7 Q. Okay. And in both cases, the black
8 specks came and went with the light, is that
9 right?

10 A. That's correct, with the orientation.

11 Q. With the orientation of the mesh?

12 A. That's correct.

13 Q. Okay. Now, when I talk about cutting
14 the mesh, what I'm referring to is you see a
15 black speck, you cut through the monofilament
16 where the black speck shows up, and do you then
17 look at it head-on and confirm that there is no
18 black speck in the middle of the monofilament?
19 Was that done?

20 A. No, it was not.

21 Q. What's the significance of -- is there
22 any significance at all to the idea that
23 Dr. Dunn saw black specks in these meshes?

24 A. I believe Dr. Dunn was seeing the same
25 thing I saw, that it's due to reflection of

1 black objects in the room rather than actual
2 inherent black specks due to processing.

3 Q. Do you know this mesh, this Polyform
4 mesh that you have, do you know what the lot
5 number was on it?

6 A. It would have been the same lot number
7 as reflected in my reports, the case-specific
8 testing.

9 Q. Okay. So the case-specific testing
10 that you did for this wave 1 and wave 2, that
11 you were supplied Polyform mesh for that, is
12 that right?

13 A. I was previously supplied Polyform
14 mesh, yes.

15 Q. Okay. And did that Polyform mesh come
16 from an Uphold, or was it just Polyform mesh?

17 A. It was just Polyform mesh.

18 Q. So you were supplied that in 2013?

19 A. I don't recall if it was 2013 or 2014,
20 but...

21 Q. So previously. So for your previous
22 report, you don't know if for your previous
23 report you were supplied Polyform, or were you
24 given it recently, or --

25 A. It was a while ago.

1 Q. Okay. So in your report, in the
2 case-specific section of your report, there's
3 going to be a reference to the lot number of
4 Polyform that you examined?

5 A. That's correct.

6 Q. And no photographs were taken, right?

7 A. That's correct.

8 Q. Do you have the mesh that you cut into
9 a square still?

10 A. I've got the same overall piece of
11 mesh, I do, yes.

12 Q. So you have the same overall piece of
13 mesh, but you don't -- do you have the
14 unravelled bits of mesh that you had?

15 A. No, I do not.

16 Q. Did you take into account any, say --
17 let's call it the incidence or the reflective
18 angle that polypropylene might have on your
19 light?

20 A. Yes, I did.

21 Q. So I may have just used the wrong
22 terminology completely. But you know how when
23 you look into a pond and you think a fish is in
24 front of you, but it's actually at a different
25 angle than it is because of the way light

1 reflects through water?

2 A. Refracts.

3 Q. Refracts through water. Did I use the
4 word -- I used it correctly, I think, the first
5 time. The second time I said reflects.

6 So did you take that into account when
7 you did your examination of the black specks?

8 A. Yes, I did.

9 Q. And how did you do that?

10 A. Again, by orienting the sample and
11 rotating it. That's exactly what's happening,
12 you're changing the angle of reflection. I can
13 also demonstrate that I could reproduce the
14 presence of the black speck by taking a piece of
15 monofilament polypropylene not related to
16 Polyform that shows no black specks, and by
17 putting a slight indent on the surface of it I
18 could create a black speck or flatten it, which
19 was changing the curvature of the fiber.

20 Q. Are you aware, did you perform this
21 examination with, say, an AMS product?

22 A. No, I did not.

23 Q. So just the Polyform mesh that you
24 have?

25 A. That's correct.

1 BY MR. BOWMAN:

2 Q. Okay. Did you have a chance to review
3 the photographs, the microscopic photographs
4 taken by Dr. Dunn in this case?

5 A. I did see some of them, yes.

6 Q. And is it your testimony that none of
7 those photographs had black specks along, you
8 know, non-curved portions of the mesh?

9 A. I don't recall seeing from his. I
10 know from my own examination.

11 Q. So your own examination is that you
12 saw the black specks in the curvature of the
13 mesh and not in the straightaways?

14 A. That's correct.

15 Q. Okay. Do you teach any classes
16 related to polypropylene mesh, Doctor?

17 A. No, I do not.

18 Q. Do you teach any classes related to
19 polypropylene?

20 A. I've given lectures on polyolefins and
21 polypropylene as part of that discussion.

22 Q. Ever discuss polypropylene mesh?

23 A. I don't recall doing it, no.

24 Q. I'm looking at your time and expense
25 detail, and it goes back to December 5th. Is

1 BY MR. BOWMAN:

2 Q. And then rinsing it with more -- after
3 it was decanted and rinsed with more hexane,
4 same purpose?

5 A. Just removing any residual, yes.

6 Q. Do you know, does hexane react with
7 polypropylene?

8 A. It does not.

9 Q. Do you know, does hexane react with
10 any of the enzymes associated with tissue
11 ingrowth or collagen formation on implantable
12 medical devices?

13 A. I don't know.

14 Q. Can you tell me what you do know about
15 collagen formation on implantable medical
16 devices?

17 MR. PRATT: Object to the form.

18 A. Not very much, no.

19 BY MR. BOWMAN:

20 Q. Do you know if there is, in human
21 collagen, if there is a ratio of carbon to
22 oxygen that is present in human collagen?

23 A. Well, the chemistry of it is well
24 described, and there would be a specific ratio.

25 Q. As a chemical engineer, is this

1 something you've looked at in the past?

2 A. We have in the past. I don't remember
3 it currently, but we worked in the area of
4 collagen in the past.

5 Q. Are you also aware that there is a
6 specific ratio of carbon to nitrogen in human
7 collagen?

8 A. Yes.

9 Q. And are you -- this is a math
10 question. Are you also aware that there is a
11 ratio of nitrogen to oxygen in human collagen?

12 A. Yes.

13 Q. Did you use this knowledge in forming
14 your opinions in this case?

15 A. No, I did not.

16 Q. Was there any literature that you
17 looked to in forming your opinions in this case?

18 MR. PRATT: Object to the form.

19 BY MR. BOWMAN:

20 Q. In regard to the ratios of carbon
21 nitrogen to oxygen that are present in human
22 collagen?

23 MR. PRATT: Object to the form.

24 A. No, I did not.

25 BY MR. BOWMAN:

1 A. No.

2 Q. Did you know if any of these women had
3 mesh removed for erosions?

4 A. No.

5 Q. You knew nothing about the specific
6 medical conditions of any of these women?

7 A. That's correct.

8 Q. Except for the fact that at some point
9 in time they had mesh implanted, is that right?

10 A. Implanted and explanted.

11 Q. Implanted and explanted. Okay.

12 How does the hexane soak work to
13 remove fatty acids?

14 A. Acids tend to be soluble in hexane.
15 So what you're making use of is basically the
16 partition coefficient of the extraction process,
17 that the fatty acids would prefer to be in
18 hexane over being in the polypropylene.

19 Q. So it's a diffusion reaction, is that
20 right?

21 A. Yes.

22 Q. So wouldn't there be a point where we
23 just got to equilibrium and there would be as
24 much fatty acid in the solution as there was in
25 the mesh?

1 A. We -- because I used an abundance of
2 hexane, so in other words a lot more hexane than
3 they could possibly -- flip that around.

4 The concentration of fatty acid in the
5 hexane solution should never get to the point
6 that it would match what's in the polypropylene.

7 Q. And what's the purpose of -- and,
8 frankly, do you have any literature that says
9 that polypropylene is going to be --
10 polypropylene mesh is going to be absorbing
11 fatty acids?

12 A. Clavé speaks to that a bit in his
13 paper, but it's well-known that implantable
14 polyolefins in general will absorb fatty acids
15 and things like squalene and cholesterol.
16 There's been publications on that.

17 Q. And those would be sort of bloodborne
18 absorptions to the mesh? How would they come in
19 contact with the mesh? That's my question.

20 A. The fact that the mesh is in contact
21 with fat, muscle, just basic biological tissue,
22 those will all contain components of fatty
23 acids, amides, proteins, etcetera.

24 Q. And when you refer to Clavé, you're
25 referring to one of his three hypothesis on -- I

1 don't even know, one of the three things that he
2 described in his paper?

3 A. Yes. He identifies absorbed fatty
4 acids or absorbed biological materials in his
5 FTIR.

6 Q. He identified absorbed biological
7 materials in his FTIR?

8 A. Yes.

9 Q. And how did he do that?

10 A. He described that the hydroxyl group
11 formation and the carbonyl formation was due to
12 biological material.

13 Q. Okay. I'm not ready to talk about
14 that, because we didn't actually talk about
15 the -- we did talk about the methods that you
16 use regarding XPS and EDS, and the difference
17 between the two of them. But as far -- and we
18 discussed the microscopy, and we described the
19 FTIR as being standard.

20 FTIR, is that a bulk measurement, or
21 is that a surface measurement?

22 A. It can be either.

23 Q. Okay. In the case of what you
24 performed -- the FTIR that you performed on
25 these -- per this protocol, what was it, a bulk,

1 zoom into high magnification for features.

2 Q. So when I'm talking about -- I'm
3 talking about a specific area. And you've
4 already testified that there are other SEM
5 images. Did you take an SEM image of every
6 square of the sample, or did you just choose
7 separate areas to take SEM images?

8 A. Our process is to first do a survey
9 scan, just move around the sample just to get an
10 idea of what the topology or morphology looks
11 like on the sample, and then to capture
12 representative images of those areas.

13 Q. Okay. And same question regarding
14 protocol, but this time for EDS. How were the
15 EDS sites chosen?

16 A. In this case, we were looking for
17 areas that had visual cracking on the surfaces
18 to identify what was the nature of the cracking
19 or what was the elemental composition.

20 Q. And do you know how far down into each
21 sample you went with the EDS?

22 A. Well, the EDS is a surface analysis.
23 And the -- so based on the accelerated voltage
24 that we're using, it will be the first few
25 microns.

1 Q. Could that differ between report, or
2 is that something that you would just have been
3 -- it would have been standardized throughout
4 all reports?

5 A. Standardized.

6 Q. Okay. And so just so I'm clear, the
7 SEMs -- we have broad sweeps of SEMs that were
8 taken of each sample, is that correct?

9 A. Not necessarily images collected, just
10 viewed.

11 Q. Okay. So images weren't collected,
12 they were viewed?

13 A. They are viewed, that's correct. And
14 then we collect representative images, which are
15 reflected in this report, or these reports.

16 Q. Okay. So for each report, every SEM
17 image that you took would have been produced in
18 that report?

19 A. Yes, I believe so.

20 Q. And for each report, the EDS that you
21 took, you looked for areas that had surface
22 cracking, and then you took an EDS reading?

23 A. In general that was the protocol, yes.

24 Q. Why did you choose that protocol?

25 A. I wanted to identify or ascertain what

1 was the nature -- what was cracking off the
2 surface, was it polypropylene, was it the
3 adhered biological material.

4 Q. Why not perform EDS on an area that
5 seemed relatively clean?

6 A. I believe I did that in some of the
7 cases as well.

8 Q. Did you do that in all the cases where
9 you had EDS?

10 A. No, I did not.

11 Q. Are there EDS readings that haven't
12 been produced for each Plaintiff, do you know?

13 A. I don't believe so, no.

14 Q. So this is a protocol that you
15 created?

16 A. It's one that we use when we're
17 looking at explanted samples. It was developed
18 over time in my laboratory.

19 Q. When you say "we," you're referring
20 to -- what are you referring to?

21 A. Cambridge Polymer Group.

22 Q. And even though you'd given me the
23 reference, the de Tayrac reference, the
24 ultrasonic bath, that's something that you had
25 in place prior to de Tayrac published?

1 A. Not the combination of DMSO and
2 ultrasonically, but individually we've used both
3 of those to clean explants.

4 Q. So the EDS, those samples weren't
5 randomized, correct?

6 MR. PRATT: Object to the form.

7 A. I'm not sure I understand.

8 BY MR. BOWMAN:

9 Q. So for each Plaintiff-specific opinion
10 that you've given on EDS, you actually chose the
11 spot where the EDS reading would be taken, is
12 that right?

13 A. Yes, that's correct.

14 Q. And in some instances, you have two
15 spectra for Plaintiffs, is that right, per
16 Plaintiff? Is that right?

17 A. I believe that's right.

18 Q. In some instances there's only one
19 spectra collected?

20 A. That's correct.

21 Q. And to the best of your ability, you
22 removed as much -- if there were any fatty acids
23 absorbed, you removed them with the hexane, is
24 that right?

25 A. Well, to the best of my ability to

1 something else. Is it your understanding that
2 it's not calcium stearate that's in there?

3 A. It's DHT.

4 You're talking about the acid
5 scavenger.

6 Q. The acid scavenger, I'm not. I'm
7 talking about a surfactant? It's something
8 for --

9 MR. PRATT: Which point are you
10 talking about now?

11 MR. BOWMAN: It's in the latest
12 report. We don't need to talk about it, I just
13 wanted to -- what I wanted to do was -- let me
14 just -- can I strike the last question? Thank
15 you.

16 BY MR. BOWMAN:

17 Q. So there are three acid scavengers, is
18 your understanding, and none of them would have
19 been pulled out by the hexane?

20 A. There is one hexane scavenger, as I
21 understand.

22 Q. I meant that.

23 There's one acid scavenger and there
24 are two antioxidants?

25 A. That's correct.

1 Q. Those are the three that you don't
2 think would be pulled out by the hexane, is that
3 right?

4 A. I'm not certain, actually. That's not
5 something I looked into in this case.

6 Q. And what about the -- what about those
7 products specifically, do they react with
8 potassium hydroxide?

9 A. Not that I know of.

10 Q. Do you know the molecular composition
11 of all three of those additives?

12 MR. PRATT: Object to the form.

13 A. I do.

14 BY MR. BOWMAN:

15 Q. And in response to my question
16 regarding hexane, in response to my question
17 regarding potassium hydroxide, have you done the
18 chemistry involved and said you don't
19 understand -- that's not your understanding that
20 those two products will react with these
21 additives?

22 A. There should be no reaction with them.

23 Q. Okay. Now, is that because they're
24 not on the surface of the mesh, or is that
25 because they are non-reactive?

1 carbonyls in either of the controls, is that
2 right?

3 A. That's correct.

4 Q. You're not registering any fatty acids
5 in either of the controls, is that right?

6 A. That's correct.

7 Q. Are you seeing any of the antioxidants
8 in either of the controls?

9 A. We probably wouldn't pick up the
10 antioxidants because they're at such low
11 concentration.

12 Q. Even with this crystal method that you
13 employed?

14 A. Yes.

15 Q. So can you tell me what is at the peak
16 between 2750 and 2700?

17 A. Sorry, say those numbers again?

18 Q. 2750 and 2700.

19 A. That's either a methylene group or a
20 methyl group.

21 Q. And as far as I can tell, that peak is
22 the exact same in both controls. Do you see
23 that?

24 A. Yeah. There's a little bit difference
25 in height, but the height is a relative thing.

1 spoke about a baseline with reference to the two
2 pristine samples, correct?

3 A. Yes, we did.

4 Q. Now we're talking about a separate
5 baseline that would be used to compare the two
6 pristine samples. Please explain.

7 A. No. Each sample, each spectra has a
8 baseline, has its own unique baseline, what is
9 effectively zero absorbance. And that baseline
10 can move up at lower wave numbers, as we see in
11 this particular sample. So if we were -- if I
12 were to have baseline corrected this spectra,
13 there would be no departure around 1750 as you
14 were observing. It would be flat there.

15 Q. Okay. But for the purposes of this
16 report, your conclusion is that no oxidation
17 peak was observed in this area, correct?

18 A. That's correct.

19 Q. But you're also saying that if a
20 baseline had been created, that I would see
21 nothing there?

22 A. It would be -- the baseline correction
23 wouldn't have changed my opinion. It's just it
24 would be -- for someone who doesn't look at FTIR
25 on a daily basis, it would be absolutely clear

1 to you.

2 Q. Okay. And you also reference minor
3 peaks between 17 and 1500.

4 Do you see that?

5 A. Yes, I do.

6 Q. And you say that these are associated
7 with Amide I and Amide II?

8 A. Yes.

9 Q. Which are found in proteins, correct?

10 A. Yes, that's correct.

11 Q. Did you do any analysis to -- specific
12 to this case that would have confirmed that?

13 A. Not specific to this case, no.

14 Q. So when we talked about Amide I and
15 Amide II, we're talking about
16 nitrogen-containing proteins, essentially?

17 A. Well, nitrogen-containing compounds,
18 proteins would be one.

19 Q. But in this area between 1700 and
20 1500, are there other things that could show up
21 on FTIR in this area?

22 A. There are other things, but those --
23 the peaks, particularly with something that's
24 been explanted, that's where amides will always
25 come out.

1 MR. PRATT: Object to the form.

2 A. No.

3 BY MR. BOWMAN:

4 Q. The potassium hydroxide is only going
5 to attack the amide groups, is that right?

6 MR. PRATT: Object to the form.

7 A. I don't know if it's even reacting
8 with the amide groups. It dissolving the
9 polypropylene -- I'm sorry. It's dissolving the
10 biological material that's there which, you
11 know, may not be effectively cleaving in bonds
12 within the proteins, but just causing it to
13 dissociate.

14 BY MR. BOWMAN:

15 Q. Dissociate with what?

16 A. From each other.

17 Q. Okay. And you already testified that
18 there's no way there could possibly be any bonds
19 between an amide group, any kind of amide group
20 and the polypropylene that is the Boston
21 Scientific polypropylene, correct?

22 MR. PRATT: Object to the form.

23 A. No. I said that there's no rational
24 chemical reaction between polypropylene and any
25 protein that might be present in the material.

1 BY MR. BOWMAN:

2 Q. Okay. And that includes the
3 antioxidants?

4 A. That's correct.

5 Q. So the antioxidants are not going to
6 react with any collagen, with any protein, with
7 anything that comes into contact with this mesh
8 over the lifetime of its implantation?

9 A. Well, if any of those have a free
10 radical, the antioxidant may donate proton to
11 those free radicals.

12 Q. So the antioxidant is going to donate
13 a proton whenever it can, correct?

14 A. Well, if it's in sufficient proximity
15 to one.

16 Q. But you're also testifying that there
17 are no free radicals in this potassium hydroxide
18 solution, correct?

19 A. That's correct, yes.

20 Q. And no free radicals are created
21 between the reaction of the potassium hydroxide
22 and the protein that's being dissolved, is that
23 right?

24 A. Say that question again, please?

25 Q. No free radicals are being created in

1 the reaction between the potassium hydroxide and
2 the amide groups that are being dissolved?

3 A. Not that I know of.

4 Q. Did you specifically investigate that?

5 A. No. That wasn't important to me in
6 this case.

7 Q. Well, if they did create free
8 radicals, wouldn't that be important to you in
9 this case?

10 A. No, it would not.

11 Q. Why not?

12 A. Because you're removing tissue on the
13 outside, you're not allowing those species to go
14 back into the polypropylene. We're just looking
15 at adherent tissue on the outside of the
16 polypropylene.

17 Q. But you -- it's a soak. You soaked it
18 for a week in the solution, right?

19 A. Yes.

20 Q. So if free radicals were created, they
21 could react with the surface of the
22 polypropylene?

23 A. It's unlikely for that to happen.

24 Q. They could react with the antioxidants
25 in the polypropylene?

1 A. Again, doubtful. You're talking about
2 things that are only proximal to the surface,
3 and you have to have intimate molecular contact
4 for that to occur.

5 Q. More intimate than being in a vial for
6 a week with sodium -- with potassium hydroxide?

7 A. Yes. We're talking on the molecular
8 level, not just sitting next to each other in a
9 vial.

10 Q. So your testimony regarding this FTIR
11 spectra is that even though you did investigate
12 the possible reaction creation of free radicals
13 with the amide groups and the potassium
14 hydroxide, that shift still would not have
15 occurred with this carbonyl?

16 A. That's correct, which is why this
17 cleaning technique is recommended in an ASTM
18 561, because we're looking for explanted plastic
19 devices.

20 Q. Polypropylene is probably the most
21 reactive plastic out there, isn't it?

22 MR. PRATT: Object to the form.

23 A. No.

24 BY MR. BOWMAN:

25 Q. Is there something that's more

1 Q. Either by tweezers, or by who knows?

2 A. Correct.

3 MR. PRATT: Object to form.

4 BY MR. BOWMAN:

5 Q. Now, when you -- could you have done
6 that?

7 A. As I said, I handled these carefully.
8 I used a plastic tweezers, which shouldn't
9 affect the polypropylene. I tried to be careful
10 with them. It's possible that there were spots
11 that I did have contact, but I was always
12 contacting the end of the samples, so I don't
13 believe that I affected that.

14 Q. So the conclusions that you've drawn
15 in all of these cases where you say it is
16 qualitatively compliant, the qualitative
17 compliance is based on your handling with
18 tweezers in open air?

19 A. That's correct.

20 Q. And you would then compare that with
21 the pristine washed mesh?

22 A. That's correct. Or the never-washed
23 mesh as well.

24 Q. I keep saying the same thing -- I
25 think we're saying the same thing.

1 that are associated with just the surface of
2 these monofilaments, right?

3 A. Sure.

4 Q. And if only 10 percent of the
5 surface -- let's say 1 percent of the surface of
6 the area that was examined under FTIR, had
7 hydroxyl groups, would that show up on the FTIR?

8 A. You can typically pick up around, with
9 all these techniques, around .5 to 1 weight
10 percent of a particular molecular group.

11 Q. Okay. And so that would be -- well,
12 in any event, it's easier to target a specific
13 area with XPS or EDS than it is for FTIR,
14 correct?

15 MR. PRATT: Object to the form.

16 A. If you want to look at a specific
17 area, you can target all the techniques with
18 that, you can get more specificity with EDS than
19 you can with XPS.

20 BY MR. BOWMAN:

21 Q. Here's a question I didn't ask.

22 On your FTIR, how did you target that?
23 How did you target your FTIR readings?

24 A. It was really just wherever I could
25 get a signal from the FTIR, so I moved the

1 crystal down in contact with the filament and --
2 to see if I got a signal or not.

3 Q. So that's the exact opposite of what
4 you did for EDS, right?

5 MR. PRATT: Object to the form.

6 A. EDS allows me to identify where
7 there's cracking and then do the EDS in that
8 location.

9 BY MR. BOWMAN:

10 Q. So if you thought there was biologic
11 material in a certain portion of a monofilament,
12 you didn't take that into account when you put
13 the FTIR on?

14 A. You can't see it under the FTIR,
15 rather like visually, the magnification is much
16 too small to see that.

17 Q. But with your naked eye, you do
18 conclude in these reports that it looked the
19 same as the never-cleaned mesh -- right,
20 never-implanted mesh?

21 A. I'm sorry?

22 Q. The cleaned, never-implanted mesh,
23 that before you did the FTIR, to your naked eye
24 they looked the same?

25 A. Visually, yes.

1 hydroxyl group is not indication of oxidation.

2 BY MR. BOWMAN:

3 Q. Okay. Well, that brings me back to
4 the question.

5 So the fact that there is a nitrogen
6 in the spectrum 32, that doesn't tell us that
7 oxygen, or an OH is not bound to the surface of
8 the polypropylene mesh, correct?

9 A. It could either be an OH bound to the
10 surface of the polypropylene, which is the
11 mechanism by which the secondary antioxidant
12 stabilizes the polypropylene, or it could be
13 through the presence of fatty acids.

14 Q. Or it could be oxidized polypropylene,
15 couldn't it?

16 MR. PRATT: Object to the form.

17 A. You'd need to see carbonyls for that
18 to be the case.

19 BY MR. BOWMAN:

20 Q. Well, again, you didn't do an FTIR on
21 the sample where you did the EDS, right?

22 MR. PRATT: Object to the form.

23 A. No.

24 BY MR. BOWMAN:

25 Q. Right. Okay.

1 group?

2 A. There was trace amounts of amide
3 groups present, but they're definitely greatly
4 reduced compared to the first cleaning step.

5 Q. And you discuss and you say, "Based on
6 the totality of my testing, the mesh was not
7 oxidized," is that right?

8 A. That's correct.

9 Q. And again, you have some very -- the
10 mesh -- there's a rather large piece of mesh,
11 and you've performed two spot checks for
12 nitrogen-based compounds by EDS, and that is
13 enough data for you to conclude that the entire
14 mesh was not oxidized?

15 A. That, coupled with the FTIR as well,
16 which was done in two different locations, yes.

17 Q. And again, the EDS does not tell you
18 whether or not there was carbon bound to the
19 surface of the mesh, does it?

20 A. I don't understand your question.

21 Q. Certainly. I mean, if we look at the
22 ratios of carbon oxygen here, this is by far --
23 the ratio here is .4 by weight of nitrogen, and
24 then we have almost -- we have 4.9 percent by
25 weight oxygen. And if we're talking about amide

1 groups, there has to be more nitrogen than that
2 associated with the oxygen, correct?

3 A. Again, with two caveats on that.
4 Quantitative EDS on these type of samples isn't
5 a very good idea.

6 And the second caveat is because we
7 have this aluminum present, that some of the
8 oxygen is going to be associated with the
9 aluminum.

10 Q. Okay. Taking into account those two
11 caveats, we don't know if there are carbonyls
12 present in the sample where you performed the
13 EDS on the surface of the mesh?

14 A. There's nothing to suggest that there
15 would be carbonyls here based on the FTIR and my
16 experience with looking at these explants.

17 Q. Have you ruled it out?

18 A. Yes.

19 Q. Based on your experience, but not
20 based on the data collected?

21 MR. PRATT: Object to the form.

22 A. Based on the data collected as well.

23 BY MR. BOWMAN:

24 Q. Even though the EDS is not the same
25 spot where the FTIR was collected?

1 A. That's correct.

2 Q. And even though the EDS represents
3 only a minute amount of the entire surface area
4 of the mesh?

5 MR. PRATT: Object to the form.

6 A. It's replicative of what's happening
7 in the other parts of the material. There's no
8 reason why one spot would oxidize differently
9 than another spot if it's going to oxidize.

10 BY MR. BOWMAN:

11 Q. Actually, there is a big reason why,
12 and it's -- you've done work and I've seen your
13 publications, and it's the fact that this
14 material becomes induced, it's the surface
15 induction of the polypropylene. You get the
16 surface induction, huge reaction takes place,
17 and then the induction begins all over again
18 with the presence of oxygen bond to the surface,
19 doesn't it, Doctor?

20 MR. PRATT: Wait. What's the
21 question? You gave a speech, and I'm trying to
22 figure out what the question is.

23 MR. BOWMAN: The question was;
24 doesn't -- the doctor's answer was -- is there a
25 way to read back the question?